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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

APR - 1 1986

Re: Cefotan
Docket No. 86E-0098

RECEIVED IN
DIRECTOR'S OFFICE

APR 8 1986

GROUP 120

The Honorable Donald J. Quigg
Commissioner of Patents and Trademarks
Washington, DC 20231

Dear Commissioner Quigg:

This is in regard to the application for patent term restoration for U.S. Patent No. 4,263,432, filed by Yamanouchi Pharmaceutical Co., Ltd., under 35 U.S.C. 156. We have reviewed the dates contained in the application and have determined the regulatory review period for Cefotan, the human drug product claimed by the patent.

The total length of the review period for Cefotan is 1,546 days. Of this time, 839 days occurred during the testing phase and 707 days occurred during the approval phase. The periods of time were derived from the following dates:

1. The date an exemption under subsection 507(d) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: October 4, 1981.

   FDA has verified the applicant's claim that the notice of claimed investigational exemption for the drug was submitted on October 4, 1981.

2. The date the application was initially submitted with respect to the human drug product under subsection 507 of the Federal Food, Drug, and Cosmetic Act: January 20, 1984.

   FDA has verified the applicant's claim that a new drug application for Cefotan (NDA 50-588) was submitted on January 20, 1984.

3. The date the application was approved: December 27, 1985.

   FDA has verified the applicant's claim that NDA 50-588 was approved on December 27, 1985.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. 156 (c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Stuart L. Nightingale, M.D.
Associate Commissioner for
Health Affairs

cc: Rosemary M. Miano, Esq.
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